

EXHIBIT 13

Work Instruction	
Status: Superseded	Effective Date: N/A
Title: JOM Customer Service Order Processing of Controlled Substance	
Doc. No. PSGA-DOC-44317	Version: 1.0

1.0 Purposes

- 1.1 To provide Customer Service with a procedure to follow when Processing daily Schedule II Orders.

2.0 Scope

- 2.1 The Scope of this WI is to provide Customer Service with process that will allow the Customer Service Rep to process Schedule II orders.

3.0 References/Related Documents

- 3.1 PSGA-DOC-42767 JOM Customer Service Searching for Customer Account Information.
- 3.2 PSGA-DOC-43461-JOM Customer Service definition document.

4.0 Definitions

- 4.1 Refer to PSGA-DOC-43461- JOM Customer Service Definition Document.

5.0 Responsibilities

- 5.1 It is the responsibility of the Customer Service Representative to follow this work instruction.
- 5.2 It is the responsibility of the Customer Service Team Leaders to assure that this work instruction is followed.

6.0 Safety and Environmental Practices

- 6.1 N/A

7.0 Equipment/Materials

- 7.1 Schedule II form.
- 7.2 Personal Computer.
- 7.3 SAP R/3 Login Access.

8.0 Procedure



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- 8.1 Schedule II team member will receive schedule II forms from Admin Assistant daily.
- 8.2 Schedule II forms will then be counted and the attached hard copy will be stamped with date received by schedule II team.
- 8.3 Date, carrier, tracking number, schedule II form number, customer name and name of Schedule II Team member that is receiving forms will then be logged on daily log located in the Schedule II locked cabinet.

SCHEDULE II - CHECK-IN LOG					
DATE	CARRIER	TRACKING NUMBER	FORM NUMBER	CUSTOMER NAME	RECEIVED BY

- 8.4 Schedule II forms will then be evenly distributed to Schedule II team members to process.
- 8.5 If a team member receives a form that does not have an attached hard copy P.O. then the team member that will be processing that order must make a copy of that form and use the copy as there hard copy P.O.
- 8.6 Schedule II team member will then check supplier information. Name of Supplier, street address, city and state, date, No. of Packages, size of package, name of item, date issued last line completed, and signature of purchaser or attorney or Agent. Ensure that Supplier's copy 1 is aligned with DEA copy 2.
- 8.7 If there are any discrepancies with Name of Supplier, street address, city and state, date, No. of Packages, size of package, name of item, date issued last line completed, and signature of purchaser or attorney or Agent. The customer must be contacted and the form must be returned to customer with a letter with explaining the reason for return.

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J • O • M PHARMACEUTICAL SERVICES

1 Cottontail Lane
Somerset, New Jersey
08873-1102

Tel: 800-631-5273
Fax: 908-302-0425



Debbie Mullen
H D Smith Wholesale Drug Co.
950 Lively Blvd.
Wood Dale, IL 60191

The Drug Enforcement Administration has established specific criteria for the acceptance of Schedule II Order Forms (DEA Form 222). In some cases, we are required to return the form and request a corrected form. Once the corrected form is received, Janssen-Ortho-McNeil Pharmaceutical can process and ship the order.

The enclosed blanks are being returned for correction to supplier information. Please resubmit naming JOM as the supplier.

- The date must not be overwritten. Please send a new form with the correct date.

Due to the specific criteria for acceptance, you must correct the text mentioned above provided on the DEA form supplier's copy 1 and DEA copy 2 and resubmit the form for processing.

Please send correct 222 form to

JOM Pharmaceutical Services
1 Cottontail Lane
Somerset, N.J. 08873

We apologize for any inconvenience and if you need further information, please feel free to contact our Customer Service Department at 800/523/6225 or 800/523/5961.

Thank You,
JOM Pharmaceutical Services
Customer Service Specialist

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- 8.8 Any form that is returned to customer must be logged in the CII Return Log book. Located in the schedule II locked cabinet.
- 8.9 If there has to be any changes made to the form you must draw a line through the item, initial and date and write cancelled in the space provided for the number of items shipped. Then you must notify the customer in writing of the cancelled line item.

8/3/05

151539

Name of supplier, City and State

Street address

Date

last line completed

Date issued must not be older then 60 days.

Customer signature

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II

103698566

Line	Qty of Packages	Brand Package	Form of Drug	Strength	Form of Drug	National Drug Code	Package Quantity	Date
1	72	100	CONCERTA	18MG ER	TY	173114 585010	72	8/3/05
2	12	100	CONCERTA	27MG ER	TY	173114 585012	12	8/3/05
3	72	100	CONCERTA	36MG ER	TY	173114 585014	60	8/3/05
4	72	100	CONCERTA	54MG ER	TY	173114 585016	72	8/3/05
5	10	10X10UD	TYLOX	500MG	CP	004510 052009	10	8/3/05
6	216	5	DURAGESIC	25MG/HR	PA	504581 003005	216	8/3/05
7	120	5	DURAGESIC	50MG/HR	PA	504581 003007	120	8/3/05
8	48	5	DURAGESIC	75MG/HR	PA	504581 003009	48	8/3/05
9	72	5	DURAGESIC	100MG/HR	PA	504581 003011	72	8/3/05

Signature of Purchaser or Agent or Receiver

AMERISOURCEBERN PHARM CORP
1003 N. SATELLITE BLVD
SUMNER, GA 30024

02282005

2, 3, 3N, 4, 5

051450258

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II

103698566

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- 8.10 Schedule II team member will then fill just the NDC codes on each Schedule II form and stamp the JOM DEA number on the supplier copy 1 and DEA copy 2 of form in the suppliers DEA registration No. field.



Number of packages ordered must coincide with manufactures selling units.

TO BE FILLED IN BY SUPPLIER		
SUPPLIERS DEA REGISTRATION No. R00194059		
National Drug Code	Packages Shipped	Date Shipped

Stamped JOM DEA number

- 8.11 Schedule II team member will then hand off schedule II forms to another schedule II team member to check NDC codes and quantities requested by customer.

<p>4239997</p> <p><i>[Handwritten initials]</i></p>	9 7
	10
	9
	Date Issued
	Schedule
Registered	0157
DEA Reg. No.	1999

Schedule II Team Members initials

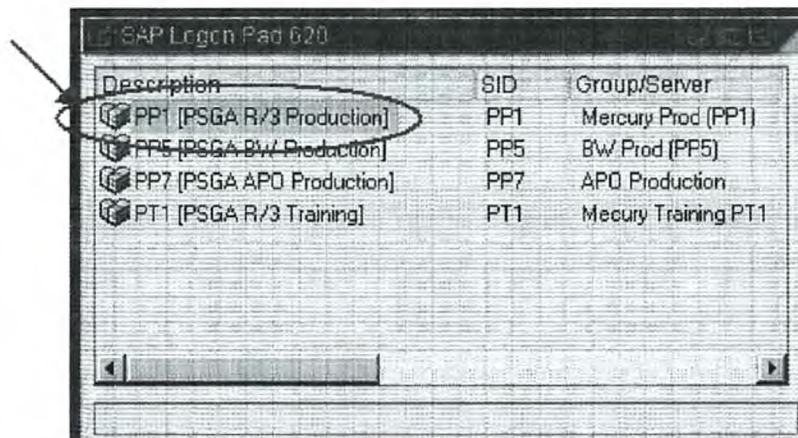
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8.12 Once other team member has checked schedule II forms for accuracy, team member will initial form on the tear away portion and return forms to original team member to process in SAP R/3.

8.13 Double-click on the SAP Logon icon on your desktop.

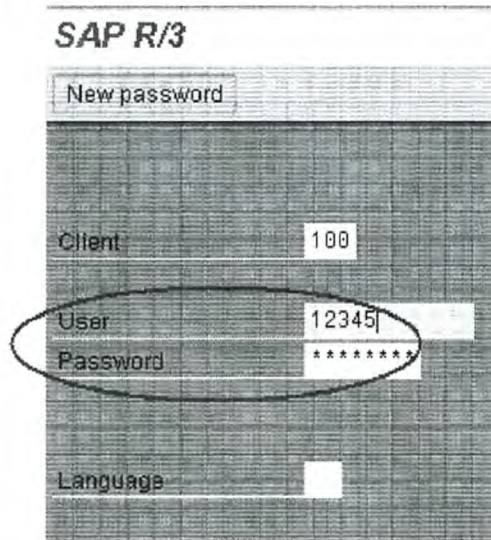


8.14 Double-click on PP1 [PSGA R/3 Production].



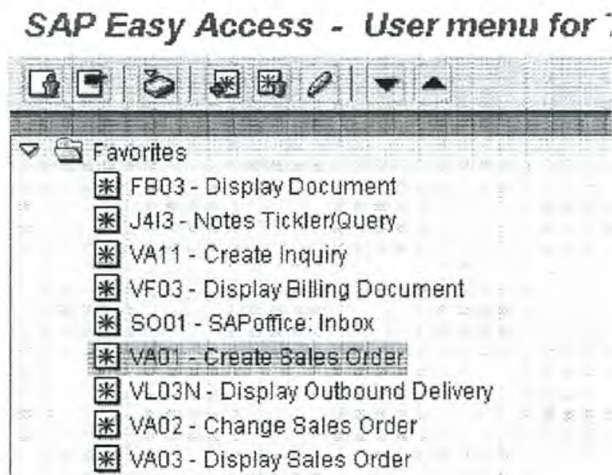
8.15 Once you have double-clicked on PP1 [PSGA R/3 Production] you will then come to the SAP R/3 login screen.

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8.16 In the User field you will enter your WWID and in the Password field you will enter your password and press enter.

8.17 Double-Click on VA01 Create Sales Order.



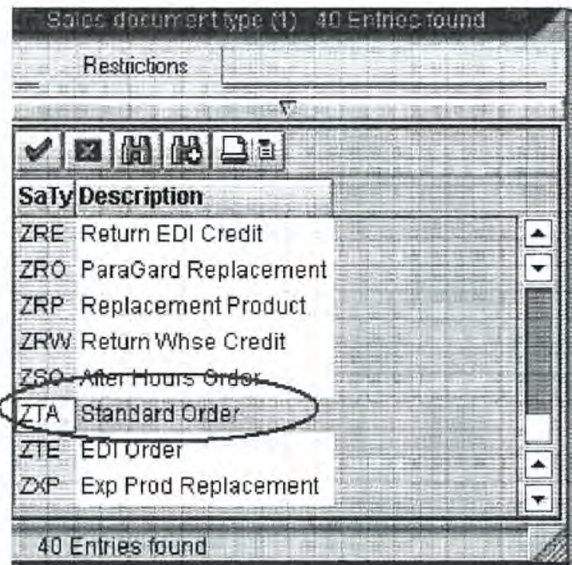
8.17.1 Once you have double clicked on (VA01 Create Sales Order). The (Create Sales Order: Initial Screen) will appear.

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- 8.17.2 In the order type field enter the order type or double click on the circle at the end of the field to display a list of options.



- 8.18 A drop down menu of transaction types will appear and you can choose your order type from there.



- 8.19 Double click the order type of the order you are processing and the order type that you have chosen will appear in the Order Type Field.



- 8.20 Once you have your order type in the order type field hit the enter key you will come to the Create Standard Order: Overview Screen.

- 8.20.1 Click the circle at the end of the Sold to party field to display Custom search Using Addr. Attrib.(address attribute) screen.

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Standard Order	
Sold to party	
Ship to party	
Purch order no.	

8.21 The search using addr. attrib. will allow you to search for the customers account by Search Term 1/2, Where you can enter the DEA number of the form you want to process.

8.22 Once you have entered the forms DEA number in the Search Terms field click on the green check mark.



8.23 The account that the search was done for will then appear on the screen.

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Customers (general)	Customers per sales group	<input checked="" type="checkbox"/> Customers by Address Attributes	Customers per a				
Customer	Name	First name	Street	House no.	Postl co...	City	Search ter...
10795	N C MUTUAL WHLSE DRUG CO		816 ELLIS ROAD		27702	DURHAM	PN0033857

8.24 Double-click directly on the on the customer line.

8.25 The account number will then appear in the Sold To Party Field:

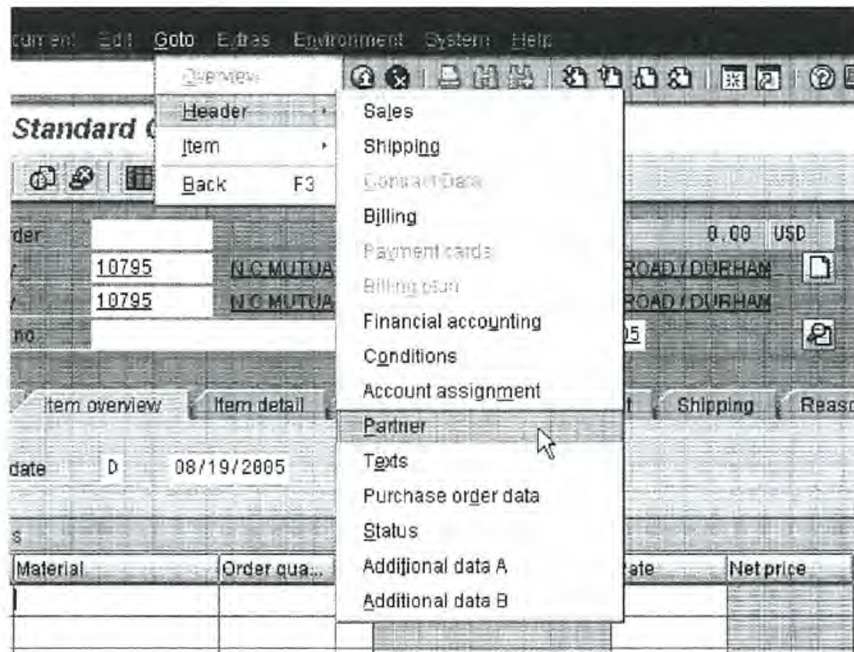
Standard Order		
Sold-to party	10795	
Ship-to party		
Purch.order no.		

8.26 Press enter and the accounts address will populate.

Standard Order		Net value	0.00	USD
Sold-to party	10795	N C MUTUAL WHLSE DRUG CO / 816 ELLIS ROAD / DURHAM		
Ship-to party	10795	N C MUTUAL WHLSE DRUG CO / 816 ELLIS ROAD / DURHAM		
Purch.order no.		PO date	08/19/2005	

8.27 At the top of the screen click on Go To, then Header then click on Partner

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8.28 This will allow you to confirm that ship to: address on the form will match the ship to: address in SAP R/3.

8.29 Double-click in the ship to: Name field.

Accounting Conditions Account assignment Partners Texts Purchase order data Status						
Disp. criteria All partners						
Partn.funct.	Partner	Name	Street	Postal c...	Loc	
Sold-to party	10795	N.C. MUTUAL WHLSE	816 ELLIS ROAD	27702	DURHAM	
Bill-to party	64311	N.C. MUTUAL WHOLES		27702	DURHAM	
Payer	10795	N.C. MUTUAL WHLSE	816 ELLIS ROAD	27702	DURHAM	
Ship-to party	10795	N.C. MUTUAL WHLSE	816 ELLIS ROAD	27702	DURHAM	

8.30 This will populate the address from master data screen, that will allow you to confirm that the address on the Schedule II form matches the address in SAP R/3.

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Address from master data: the Ship-to party (Document header)

Name	
Title	
Name	N C MUTUAL WHLSE DRUG CO
Street address	
Street/House number	816 ELLIS ROAD
District	DURHAM
Postal code/City	27702 DURHAM
Country	US USA Region NC North Carolina
Time zone	EST Jurisdict. code 3406302701
Transportation zone	NC North Carolina
PO box address	
P.O. Box	
Postal code	
Company postal code	

- 8.31 Once the address is confirmed correct, click on the "X" in the upper right, then click the back arrow button to return to the Create Standard Order: Overview Screen to begin processing order.




- 8.32 Click on the Purchase order number field.

Purch. order no.	
------------------	--

- 8.33 You will then enter your purchase order and purchase order type.


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
Accounting		Conditions		Account assignment	
Sold-to party					
P.O. number	123456				
Purchase order date	08/19/2005				
Purchase order type	MAIL 				
Last contact date					
Name					
Your reference					
Telephone	919-596-2151				

8.34 Once you have entered the Purchase Order number and the purchase order type click the back arrow button.



8.35 You will then come to the Create Standard Order: Overview screen where you can enter the NDC codes and requested order quantities.

 Display Standard Order 42199747: Overview

     Orders

Standard Order	42199747	Net value	113,535.24	USD
Sold-to party	10995	AMERISOURCEBERGEN DRUG CORP / 1095 SATELLITE BLV.		
Ship-to party	10995	AMERISOURCEBERGEN DRUG CORP / 1095 SATELLITE BLV.		
Purch. order no.	040865497	PO date	08/01/2005	

Sales | Item overview | **Item detail** | Ordering party | Procurement | Shipping | Reason for rejection

Req. deliv. date: D 08/01/2005 Deliver. plant:

Item	Material	Order qua.	U	Description	Rate	Net price	per	UoM	Net value
10	1731458502	72 EA		CONCERTA 18MG 100 BOTTLE	254.00	254.00	1 EA		18,288.00
20	1731458532	12 EA		CONCERTA 27MG 100 BOTTLE	260.00	260.00	1 EA		3,120.00
30	1731458512	60 EA		CONCERTA 36MG 100 BOTTLE	260.00	260.00	1 EA		15,600.00
40	1731458522	72 EA		CONCERTA 54MG 100 BOTTLE	292.00	292.00	1 EA		21,024.00
50	0045052079	10 EA		TYLOX 500MG HUD 10X10X10"	141.78	141.78	1 EA		1,417.80
60	5045063305	210 EA		DURAGESIC 5X25MCG/HR	64.15	64.15	1 EA		13,650.00
70	5045063406	120 EA		DURAGESIC 5X50MCG/HR	117.26	117.26	1 EA		14,071.20
80	5045063505	40 EA		DURAGESIC 5X75MCG/HR	178.87	178.87	1 EA		7,154.80
90	5045063605	72 EA		DURAGESIC 5X100MCG/HR	237.39	237.39	1 EA		17,092.08

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8.36 Once the NDC codes and order quantities have been entered. Press enter to confirm that pricing matches the hard copy purchase order. Before posting/saving the order double check that the purchase order number is correct and the dollar values match the hard copy purchase order.

42199747

AMERISOURCEBERGEN PURCHASE ORDER								
PO# ACCOUNT NUMBER	PURCHASE ORDER NUMBER	DATE	DEA NUMBER	PAGE				
	040865497	07/28/05	RA0291170	1				
RENDER AVAILABLE PROMOTIONAL ALLOWANCES, FREE GOODS, SPECIAL DISCOUNTS AND DATING.								
Above Purchase Order number must appear on invoice, bill of lading and all labels								
79543 XU \$C	TO: J-G-M PHARM SERVICES/HARC		AmerisourceBergen PLEASE MAIL INVOICE IN DUPLICATE TO: PO Box 247, Thorofare, NJ 08086					
	ONE COTTONTAIL LANE SOMERSET NJ 08875-1102 TEL: (800)631-5273 FAX: (908)302-0425							
QUANTITY ORDERED	VENDOR PROD CODE	PRODUCT DESCRIPTION	STRENGTH	FORM	UP	UNIT SIZE	NDC/CPC NUMBER	ABC CODE
	HARCOTIC ORD	ER BLANK NUMB	ER 9999999	99				
72 EA	585902	CONCERTA	18MG ER	TAB		100	17314 5850 2	932546
12 EA	585302	CONCERTA	27MG ER	TAB		100	17314 5853 2	461858
72 EA	585102	CONCERTA	56MG ER	TAB		100	17314 5851 2	932756
72 EA	585202	CONCERTA	54MG ER	TAB		100	17314 5852 2	337194
10 EA	052679	TYLOX	500MC	CAP	D	10X10	0845 0524 79	488476
216 PK	003505	DURAGESIC	25MCG/HR	PAT		5	50458 033 05	654657
120 PK	003605	DURAGESIC	50MCG/HR	PAT		5	50458 034 05	654665
48 PK	003505	DURAGESIC	75MCG/HR	PAT		5	50458 035 05	654673
72 PK	003605	DURAGESIC	100MCG/HR	PAT		5	50458 036 05	654681
RECEIVED AUG 8 2005 CUSTOMER SERVICE DEPT.								
NOTE: BACK ORDER ALL SHORTS					694	116,753.29		
* Please ship the above merchandise subject to the terms and specifications stated herein. Shipments received after the 25th of the month will be considered the 1st of the month for discount purposes. Invoices for this shipment will be approved for payment after receipt of merchandise. * During the performance of this contract for purchase order, the contractor/divender agrees to comply with all federal, state and local laws respecting discrimination in employment and non-regulation of facilities including but not limited to, requirements set out at 41 CFR 60-1.4, 60-200.5 and 60-741.4, which apply (appropriately) clauses are hereby incorporated by reference.								
SHIP TO		ABC ATLANTA DIVISION			CLAY SAUNDERS			
		1085 N. SATELLITE BLVD.			GUYF2			
		SOMMERSET CA 94064						

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8.37 Click on the save button to save order in SAP.



8.38 Your order will then be assigned a confirmation number. Record the confirmation number on the tear-away portion of the Schedule II form and on hard copy of purchase order.

Confirmation number

54151529

8/3/05

42099917

JANSEN J	
CITY and STATE	
SOMERSET	
No.	Two of
1	72
2	12
3	72
4	72
5	10
6	216
7	120
8	48
9	72
10	
0223	
273	
DISTRICT	

8.39 Once team member has completed all schedule II orders form numbers that were completed that day they must be recorded in the schedule to form log on the L drive.

Address: L:\JOM\Customer Service\Teams\Schedule 2 team

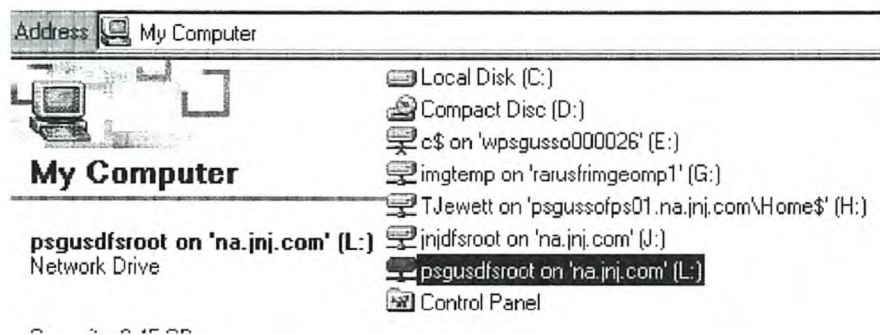
Schedule2For
ms.exe

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8.40 Go to your desktop and click on the My Computer icon.



8.41 Double-Click on the psgusdfsroot on 'na.jnj.com' (L:)



8.42 Then double-click on the JOM folder



8.43 Then double-click on the Customer Service folder



8.44 Then double-click on the Teams folder



8.45 Then double-click on the Schedule II team folder



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Schedule2For
ms.exe

8.46 Then double-click on schedule 2 forms . This will open the Schedule II Team Log-in program.

Schedule 2 Forms

Enter A New Schedule 2 Form:

Customer Service Specialist:

Schedule 2 Form Number:

Form Entry Date:

8 /25/2005

Submit

Search Existing Forms...

Other Tasks...

Exit

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8.47 Choose your name from the Customer Service Specialist dropdown menu.

Enter A New Schedule 2 Form:

Customer Service Specialist:

Claudia Lobycz

 Diane Friedman

 Essie Watson

 Grace Baez

 Jason Boorman

 Jennifer Nieratko

 Julie Basile

 Kathy Wallace

8.48 Once you have chosen your name then enter the form number and click on submit.

Customer Service Specialist:

Schedule 2 Form Number:

Form Entry Date:

Submit

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8.49 Each team member will then separate forms from hard copy purchase orders, stamp "file" on the hard copy and bring to our imaging dept. to be scanned. Schedule II forms will then be brought to locked Schedule II cabinet awaiting editing.

FILE AmerisourceBerg
 02 PLEASE MAIL
 INVOICE IN DUPLICATE
 PO Box 247, Thorofare.

8.50 Once all orders have been entered into SAP R/3. Schedule II team member collects all Schedule II forms from locked schedule II cabinet.

8.51 Log-in Sap R/3 and double-click on the "ZSCH2ORD"

- ☒ VA05 - List of Sales Orders
- ☒ VA07 - Compare Sales - Purchasing (Order)
- ☒ VA08 - Compare Sales - Purchasing (Org.Dt.)
- ☒ ZDEDUCT - Deduction Form
- ☒ ZSCH2ORD - Schedule II Order Report

8.52 On the schedule II Orders report screen, the date will automatically default to the current date.



8.53 Click on the execute button.

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Schedule II Orders SAP

System: PP1 Schedule II Orders Date: 06/25/2005
Client: 100 (ZORRORR2) Time: 06:52:05
User: 185341 Page: 1

Document #	Document Date	Account	Name Street City	DEA Number	222 Form #	Form Date
Item Description	Product Code	Order Qty/UM	Del Note Date	Qty	SI Date	
42212007	06/25/2005	119830	ALZA CORPORATION 700 EUBANKS DR VACAVILLE	RA0156376	123	06/25/2005
010	CONCERTA, 36MG, 30 CNT, SEP 24 MONTH EXP	0015030	1,723.000	EA	54168376 06252005	1,723.000
42212029	06/25/2005	10254	BELLCO DRUG CORP 5500 NEW HORIZONS BLVD NORTH AMITYVILLE	P80634061	054333972	06/16/2005
010	CONCERTA 18MG 100 BOTTLE	1731458502	12.000	EA		0.000
020	CONCERTA, 36MG, 100 COUNT BOTTLE, US	173145851224	48.000	EA		0.000
030	CONCERTA, 54 MG, 100 COUNT BOTTLE, US	173145852224	24.000	EA		0.000
040	CONCERTA 27MG 100 BOTTLE	1731458532	12.000	EA		0.000

8.54 It may take a while for the report to appear on your screen. Once the report has been generated click on the print icon.



Print icon

8.55 Delete the default setting for the output device and then click on the drop down menu button.

Schedule II Orders

Continue User-specific print parameters

Output device: PRN ID 2710

Number of copies: 1

Drop down menu

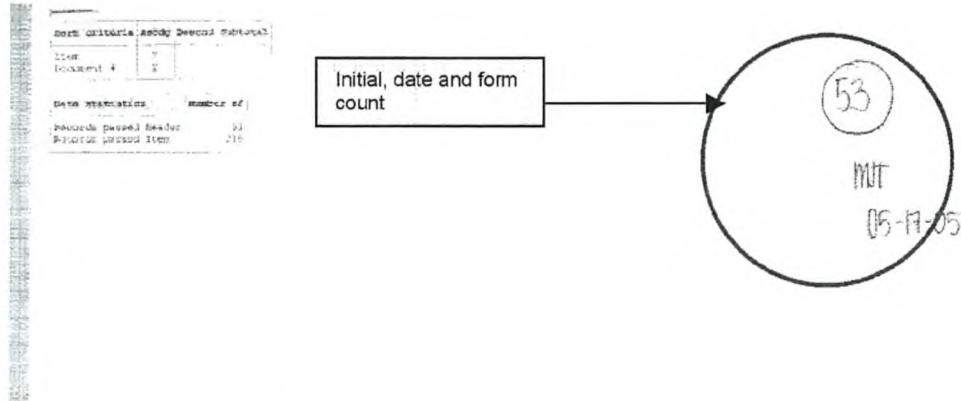
8.56 From the drop down menu choose the printer associated with you with your PC and print report.

8.59 If an error was identified on the Schedule II order form and can be corrected, the Schedule II order form will be returned to the original CSR to modify the order in compliance to DEA regulations.

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- 8.60 Once all Schedule II forms have been compared to order report.
Schedule II team member will initial, date and count forms and record that information on the first page of report.

8.61



- 8.62 Then, notify team leader that all Schedule II orders have been processed as well as the number of how many were processed for that day.
- 8.63 Schedule II team member will then store report and forms in locked schedule II cabinet.

9.0 Appendices/Attachments

9.1 N/A

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History of Change

Version Number	Change Control Number	Section	Reason for Revision (Description of Change)
1.0	CR-8887	ALL	Create work Instruction
1.0	CR-8887	8.9	Added Section 8.9

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APPROVAL PAGE

[illegible]

Work Instruction	
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Doc. No. PSGA-DOC-45016	Version: 1.0

1.0 Purpose

- 1.1 To define a process that complies with the DEA requirement to provide information on controlled substance orders considered potentially suspicious or excessive.

2.0 Scope

- 2.1 The scope of this work instruction is to cover identifying and tracking potentially suspicious or excessive narcotic orders.

3.0 References/Related Documents

- 3.1 PSGA-DOC-42786, JOM Customer Service Order Processing (VA01)
- 3.2 PSGA-DOC-42925, JOM Customer Service 10 Step Order Accuracy List
- 3.3 PSGA-DOC-7769, JOM Customer Service DPDP Execution & Customer Communication Process
- 3.4 Records Management Program for the Global J&J Pharma sector at <http://gis.prius.inj.com/recmgt/>
- 3.5 PSGA-DOC-44317, JOM Customer Service Order Processing of Controlled Substances
- 3.6 PSGA-DOC-45416, JOM Customer Service Schedule II Demand Adjustment Form

4.0 Definitions

- 4.1 SAP R/3 is the order-to-cash system used to process customer orders.
- 4.2 DEA - Drug Enforcement Administration
- 4.3 DPDP – Direct Purchasing & Distribution Policy



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- 4.4 DPDP Daily Exception Report – Report that automatically identifies orders where the ordered quantity requested exceeds the permitted quantity allowed.
- 4.5 RMD - Raw Mean Demand is a calculation provided by the DPDP Open Order Daily Exception Report, and is a representation of the historical weekly order average over a 52-week period.

5.0 Responsibilities

- 5.1 It is the responsibility of the DPDP Coordinator to follow this work instruction for identifying potentially suspicious or excessive narcotic orders.
- 5.2 It is the responsibility of the Customer Service Team Leader to ensure this work instruction is followed.
- 5.3 It is the responsibility of the JOM QA Representative to report any potentially suspicious or excessive narcotic orders to the DEA as identified by this process.

6.0 Safety and Environmental Practices

- 6.1 N/A

7.0 Equipment/Materials

- 7.1 SAP R/3 Order Processing Database
- 7.2 Business Warehouse Reports

8.0 Procedure

- 8.1 Identifying potentially Suspicious or Excessive Narcotic Orders (Schedule II & III)
 - 8.1.1 Generate the DPDP Open Orders Daily Exception Report (reference PSGA-DOC-7769, JOM Customer Service DPDP Execution & Customer Communication Process). Sort and separate Schedule II and Schedule III product information and then paste data onto an electronic worksheet. Note the date it was created. Title the worksheet "Controlled Substance Order Alert."

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- 8.1.2 Divide the Order Quantity by the RMD (Raw Mean Demand) for each Schedule II and Schedule III product to determine percent variance based on historical data and transfer this information onto the Controlled Substance Order Alert worksheet.
- 8.1.3 Sort the data according to the % variance value.
- 8.1.4 Highlight any order with a % variance value greater than 3x the customer's average order over a 52-week period.
- 8.1.5 For all narcotic orders that are viewed as potentially suspicious or excessive, the customer will be contacted via telephone by a Schedule II Team Member to request an explanation for the increased demand and change in order pattern utilizing the Schedule II Demand Adjustment form.
- 8.1.6 Customer Service is to adhere to the following script when contacting the customer:
 - 8.1.6.1 "JOM is committed to complying with all DEA guidelines and regulations. Part of that commitment requires us to identify suspicious or excessive orders and notify the DEA accordingly. We have noticed this week's order has exceeded your normal demand by X%. Please provide the reason for your increase in demand on the Schedule II Demand Adjustment Form. Again, this request is to ensure compliance with the DEA."
- 8.1.7 The Schedule II Team Member will enter all customer information on the Schedule II Demand Adjustment form and provide to the customer via fax or email.
- 8.1.8 The customer will sign and return the Schedule II Demand Adjustment form noting a detailed explanation for the increase in demand.
- 8.1.9 The Schedule II Team Member will note the customer explanation on the Controlled Substance Order Alert worksheet.

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- 8.1.10 Should the customer refuse to provide an explanation for the increase in demand or fail to return the completed Schedule II Demand Adjustment form, the Schedule II Team Member will explain to the customer that the order cannot be shipped until clearance is received from a JOM QA Representative.
- 8.1.11 The Controlled Substance Order Alert worksheet and the Schedule II Demand Adjustment form will be saved twice daily in the Schedule II Team shared drive (L-drive) as well as forwarded electronically to a JOM QA Representative so that it can be reviewed to determine which orders are potentially suspicious or excessive. The URL for the file is:
- \\na.jnj.com\psgusdfsroot\JOM\Customer Service\Teams\Schedule 2 team*
- 8.1.12 The Controlled Substance Order Alert worksheet and the Schedule II Demand Adjustment form will be saved for a period of (2) two years.
- 8.1.13 A JOM QA Representative will review the Controlled Substance Order Alert worksheet and Schedule II Demand Adjustment form to determine if the customer's explanation for the increased demand and change in order pattern is an acceptable explanation. The JOM QA Representative will then determine which orders need to be reported to the DEA within one business day.
- 8.1.14 All orders on the Controlled Substance Order Alert worksheet will be held until the completed Schedule II Demand Adjustment form is received from the customer. JOM QA will advise the Schedule II Team Member via email as to which orders can be released for shipment based on the reason noted on the Schedule II Demand Adjustment form.
- 8.1.15 A JOM QA representative will sign the completed Schedule II Demand Adjustment Form and return it to Customer Service to be filed with the Controlled Substance Order Alert Worksheet.

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8.2 DEA Notification

- 8.2.1 The JOM QA Representative will notify the DEA via fax within one business day any orders have been identified as suspicious or excessive.
- 8.2.2 The JOM QA representative will provide the Controlled Substance Order Alert worksheet to the DEA on a bi-weekly basis noting all orders that have exceeded the permitted quantity by 3 times the normal mean demand and the reasons for the demand increase. (Refer to step 8.1.2)
- 8.2.3 The following documents will be stored in the Schedule II cabinet for a period of two (2) years for future review per the Records Management Program for the Global J&J Pharma sector, <http://gis.prius.inj.com/recmgt/>
 - 8.2.3.1 Controlled Substance Order Alert worksheet
 - 8.2.3.2 JOM Customer Service Schedule II Demand Adjustment Form
 - 8.2.3.3 DEA Notification occurring same day
 - 8.2.3.4 DEA Notification occurring bi-weekly

9.0 Appendices/Attachments

- 9.1 N/A

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History of Change

Version Number	Change Control Number	Section	Reason for Revision (Description of Change)
1.0	CR-9017	All	Creating a new Work Instruction

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APPROVAL PAGE

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Standard Operating Procedure	
Status: Superseded	Effective Date: N/A
Title: JOM Customer Service Schedule II-V Order Processing and Investigating Suspicious or Excessive Narcotic Orders.	
Doc. No. PSGA-DOC-46312	Version: 1.0

1.0 Purpose

- 1.1 To provide instructions for processing Schedule II -V orders and Investigating Suspicious or Excessive orders.

2.0 Scope

- 2.1 This SOP defines the guidelines for processing Schedule II-V orders and Investigating Suspicious or Excessive orders.

3.0 References/Related Documents

- 3.1 PSGA-DOC-44317, JOM Customer Service Processing Orders for Controlled Substances.
- 3.2 PSGA-DOC-44938, JOM Customer Service Logon, Logoff Procedure for SAP R/3.
- 3.3 PSGA-DOC-44930, JOM Customer Service Investigating Loss, Theft and Shortages.
- 3.4 PSGA-DOC-45016, JOM Customer Service Suspicious or Excessive Narcotic Order.
- 3.5 PSGA-DOC-44310, JOM Customer Service Applying DPDP *Direct Purchasing & Distribution Policy* to Schedule II Orders).

4.0 Definitions

- 4.1 (ZSCHED Report) is a transaction in SAP R/3 that will allow you to run a report for all the Controlled Substance orders enter in SAP on any given day.
- 4.2 DPDP is for JOM's Direct Purchasing & Distribution Policy. DPDP is the daily process that all orders must go through prior to being released from manager's hold. (Refer to PSGA-DOC-44310 JOM Customer Service Applying DPDP *Direct Purchasing & Distribution Policy* to Schedule II Orders)
- 4.3 PSGA-DOC-43461 JOM Customer Service Definition Document.

5.0 Responsibilities



Standard Operating Procedure	
Status: Superseded	Effective Date: N/A
Title: JOM Customer Service Schedule II-V Order Processing and Investigating Suspicious or Excessive Narcotic Orders.	
Doc. No. PSGA-DOC-46312	Version: 1.0

- 5.1 It is the responsibility of the JOM Customer Service Schedule II Team member who enters Schedule II narcotic orders in SAP R/3 to follow this to follow this procedure and related Work Instructions.
- 5.2 It is the responsibility of the JOM Customer Service Team Leader to ensure this SOP is followed.

6.0 Procedure

- 6.1 The Schedule II Team Member will process daily mailed in orders.
- 6.2 Orders that are not Schedule II's will be entered into SAP R/3 as a Standard orders (Refer to PSGA-DOC-42769 JOM Customer Service Standard Orders (ZTA).
- 6.3 Orders that are Schedule III thru V are Controlled Substances and will go through the Excessive or Suspicious process. (Refer to PSGA-DOC-45016 JOM Customer Service Suspicious and Excessive Narcotic).
- 6.4 Once Schedule II orders are entered into SAP R/3 another Schedule II Team Member will run the (*zsched report*) to check all Schedule II Orders that were entered into SAP that day against actual Schedule II form (Refer to PSGA-DOC-44317, JOM Customer Service Processing Orders for Controlled Substances).
- 6.5 If there are any discrepancies on the Schedule II forms verses the (*zsched report*) from SAP R/3, the Schedule II Team Member will notify the team member that entered the order so that it can be corrected. The Team Leader will also be notified of any forms that need to be corrected.
- 6.6 All Schedule II orders are put on Business Manager's hold.
- 6.7 Orders are then put through the DPDP process.
- 6.8 After the DPDP process each order will go through the Suspicious or Excessive ordering process. (Refer to PSGA-DOC-45016 JOM Customer Service Suspicious and Excessive Narcotic).
- 6.9 Customers must be contacted on orders that have been tagged being Suspicious or Excessive (Refer to PSGA-DOC-45016 JOM Customer Service Suspicious and Excessive Narcotic).

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6.10 Orders that are deemed suspicious or excessive will be forwarded to QA/Quality Assurance for evaluation and determination of DEA reporting requirements.

6.11 Once the order process is complete. Orders will then be released off the business manager's hold. A delivery note will create and the order will ship as normal.

7.0 Appendices/Attachments

7.1 N/A

Standard Operating Procedure	
Status: Superseded	Effective Date: N/A
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Doc. No. PSGA-DOC-46312	Version: 1.0

History of Change

Version Number	Change Control Number	Section	Reason for Revision (Description of Change)
1.0	CR-9326	ALL	Create a new SOP

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